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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,196	04/20/2004	Marlene Bainbridge	BC-0234-US04	3195

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GAMBRO, INC
PATENT DEPARTMENT
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LAKEWOOD, CO 80215

EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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08/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/709,196

Applicant(s)

BAINBRIDGE ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 29-34 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-18, 21-23, 25, 26, 29-34 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 9-13, 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 29-31 are objected to because of the following informalities: the claims depend from a cancelled claim. Claims 29-31 are being interpreted by the examiner as depending from claim 25, not cancelled claim 27. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-8, 15-18, 22-23, 25-26, 29-34, and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,072,769 to Fletcher-Haynes et al.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In the specification and figures, Fletcher-Haynes discloses the apparatus and method as claimed by applicant. With regard to claims 1, 21-23, Fletcher-Haynes discloses a method for extracorporeal blood collection from a patient comprising the steps of using a series of donor characteristics to generate a list of procedure types, selecting a procedure type from the list, and performing the selected procedure by removing, flowing, separating, collecting, and returning blood components to the patient in the manner claimed by applicant (see columns 29-30, 45-46).

With regard to claims 2 and 39, Fletcher-Haynes discloses the step of selecting an appropriate tubing and bag set as a part of the procedure (see column 12, lines 50-59).

With regard to claim 3, Fletcher-Haynes discloses that plasma may be collected after RBC separation (see column 46, lines 44-54).

With regard to claim 4, Fletcher-Haynes discloses that RBC collection may be performed after plasma separation in an embodiment of the procedure (see column 47).

With regard to claims 5-6, Fletcher-Haynes discloses that the extracorporeal blood processing machines may be connected to a central input station 140 such that the entire combination may be categorized as a blood component collection control and information communication system (see column 29). The input data station accepts patient data and generates a list of apheresis procedures based on entered patient parameters. Therefore, the combined system, including the input station and the collection system, operates as claimed by applicant, meeting the limitations of the claims.

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With regard to claims 7-8 and 15, patient characteristics used in the procedure may comprise donor height/weight, platelet count, and hematocrit (see column 27, line 48 to column 29, line 34).

With regard to claims 16-18, Fletcher-Haynes discloses that the apheresis procedure may comprise single platelets or double platelets (see column 53, lines 45-65).

With regard to claims 37 and 38, Fletcher-Haynes discloses the step of generating a new list of procedures based on changed variables (see column 29, lines 20-62).

Applicant's language in claim 25 appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for..." as reproduced above, as a controller that performs the claimed function. Accordingly, the examiner is interpreting

the “means for” passage to encompass such a controller and its equivalents. Equivalent structures may include

- a) those that perform the function specified in the claim,
- b) structures that are not excluded by any specific definition provided in the specification for an equivalent, or
- c) a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

Fletcher-Haynes discloses an apparatus that performs the function specified in the claim (see rejection of claim 1, above). Applicant does not exclude the apparatus and controller disclosed by Fletcher-Haynes as an appropriate equivalent, and the Fletcher-Haynes device is structurally equivalent to the device claimed by applicant. Accordingly, the device disclosed by Fletcher-Haynes anticipates applicant's claimed device.

With regard to claims 25-26, Fletcher-Haynes discloses a method for extracorporeal blood collection from a patient comprising the steps of using a series of donor characteristics to generate a list of procedure types, selecting a procedure type from the list, and performing the selected procedure by removing, flowing, separating, collecting, and returning blood components to the patient in the manner claimed by applicant (see columns 29-30, 45-46). Fletcher-Haynes discloses the step of selecting an appropriate tubing and bag set as a part of the procedure, indicating that the device may use a plurality of tube set options (see column 12, lines 50-59) .

With regard to claims 29-31, patient characteristics used in the procedure may comprise donor height/weight, platelet count, and hematocrit (see column 27, line 48 to column 29, line 34).

With regard to claims 32-34, Fletcher-Haynes discloses that the apheresis procedure may comprise single platelets or double platelets (see column 53, lines 45-65).

Allowable Subject Matter

4. Claims 14, 19, and 20 are allowed.
5. Claims 9-13 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the method claimed by applicant.

With regard to claims 9-14, Fletcher-Haynes discloses the method substantially as claimed by applicant (in particular the steps of using patient parameters to generate a list of component collection procedures, using the generated list to select a collection procedure, and collecting blood according to the selected procedure), but fails to disclose any steps in the procedure concerned with the packing factor of the red blood cells. Since the Fletcher-Haynes reference is commonly owned with the instantly claimed device and method at the time of invention (as stated by applicant's

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representative), the reference is unavailable for use in a 35 USC 103 rejection under the 35 USC 103(c) exception.

With regard to claim 24, Fletcher-Haynes fails to disclose the step of recirculating uncollected components within the apheresis system, along with the other steps and limitations of the claim.

With regard to claims 19-20, Fletcher-Haynes fails to disclose the step of delivering a replacement fluid manipulated by the anticoagulant flow rate as claimed by applicant, along with the other steps and limitations of the claims.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 6,602,179 Headley et al
 - i. Apheresis procedure with replacement fluid including anticoagulant

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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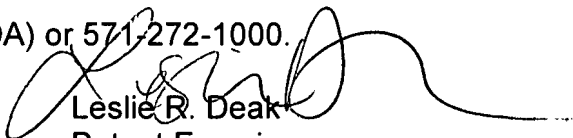
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER



Leslie R. Deak
Patent Examiner
Art Unit 3761
6 August 2007